



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Dr. Mate Brstilo
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Ministry of Agriculture and Forestry
Ulica grada Vukovra 78
10000 Zagreb, Croatia

JUL 20 2001

Dear Dr. Brstilo:

The Food Safety and Inspection Service has completed an on-site audit of Croatia's meat inspection program. The audit was conducted from December 4 – 12, 2000. Enclosed is a copy of the final audit report. Croatia's comments on the draft final audit report have been included as Attachment G. I apologize for the delay in providing this report to you.

If you have questions regarding the audit or need additional information, please contact Richard Brown at 202-720-6400. The fax number is 202-720-7990.

Sincerely,

Sally Stratmoen, Chief
Equivalence Branch
International Policy Staff
Office of Policy, Program Development
and Evaluation

Enclosure



AUDIT REPORT FOR CROATIA

DECEMBER 4 THROUGH DECEMBER 12, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Republic of Croatia's meat inspection system December 4 through December 12, 2000. Two establishments certified to export meat product to the United States were audited. Both were slaughter and processing establishments.

The last on-site audit of Croatia's inspection system was conducted in November 1999. Two establishments (10 and 139) were on-site audited. Inspection system monitoring and control records, and establishment system documents were also audited. Establishment 10 was acceptable. Establishment 139 was determined marginally acceptable and recommended for re-review by the inspection service. The following deficiencies were cited during the previous audit:

1. Pathogen Reduction (PR). Incorrect use of the incision method evaluation criteria for Sponging method for sampling *Escherichia coli* (*E. coli*) was used, and excision-sampling criteria were being used for evaluation of test results in establishments in both establishments 10 and 139.
2. SSOPs, and performance standards for sanitation, facilities and equipment.
 - a) Establishment 139
 - 1) Pre-operational and operational sanitation operating procedures were not delineated; employees street clothes inadequately covered during exposed product handling; waste receptacles covers were hand operated; dirty saw cord was touching carcasses; carcasses were touching work-stands; deboned product conveyor belt was damaged; knife sterilizer was inoperative in suspect cooler; and a wall in processing area was in poor repair.
 - 2) Carcasses were contaminated by contacting dirty surfaces of an elevated platform's protective fence; trimming at final rail was not being performed; incidentally dropped meat was being insanitarly handled, and a carcass retrieved off the floor was not properly trimmed; and the fecal and hair contamination was not being properly trimmed after the final rail inspection.
 - b) Establishment 10
 - 1) Exposed product conveyor belt was damaged; insanitary product handling and inadequate protection against work-stands touching carcasses; and carcasses were contaminated with grease/lubricant in the holding cooler.
 - 2) Employees were washing hands in dirty water in slaughter area, and carcass-splitting saw was not sanitized after repair.
3. Intra-laboratory check samples for residue and microbiological analyses were inadequate.

4. Species identification testing was not being done.

The Croatian inspection system officials stated that corrective measures had been initiated to prevent the recurrence of deficiencies noted during the previous FSIS audit in November 1999. However, this audit revealed inconsistencies in the HACCP plan and its implementation, lack of evaluation criteria for sponging method for *E. coli* testing, lack of procedures for incidentally dropped carcasses or meat, and failure to conduct species identification testing were still noted.

During January to October 31, 2000, Croatia exported 1,166,880 pounds of cured/canned pork (ham and shoulders), cooked/canned beef, pasteurized canned hams and picnics, and canned varied combination product to the United States. At the U.S. port of entry on reinspection there was no rejection.

PROTOCOL

The on-site review was conducted in four parts. One part involved visits with the Croatian national meat inspection officials at Zagreb headquarters to discuss oversight programs and practices, including enforcement activities. The second part entailed on-site audit of establishments 10 and 139 certified for export to U.S. The third part was visits to and review of records maintained at the national headquarters, at the District veterinary health control stations, and auditing of operations and documents in Croatian Institute for Veterinary Medicine (residue and microbiological testing departments), Zagreb, and two regional laboratories located in Rijeka and Krizevci. The fourth part included a visit to a livestock farm to verify animal husbandry practices including proper use and monitoring/control of antibiotics, drugs, and other regulated chemicals or compounds.

Croatia's inspection program effectiveness determination focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation of HACCP systems, and the *E. coli*, *Salmonella* species and *Listeria monocytogenes* testing program, and (5) compliance enforcement controls, including the testing program for species identification.

Emphasis was placed on verification of information provided by Croatia in response to FSIS questionnaire on 'Residue Control and Testing Program, which included laboratory testing, intra- and inter-agency legislation and regulatory authority, and compliance enforcement.

During on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/ adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Croatia has an effective national animal health and residue control programs.

At the time of audit, both U.S.-certified establishments (10 and 139) were acceptable. However, inconsistencies were noted in PR/HACCP plan and its implementation. These included, (1) not conducting statistical analysis, and establishing evaluation criteria for *E. coli* (sponging method) results, (2) not meeting requirements for ready-to-eat product testing for *Listeria monocytogenes*, (3) not conducting product pre-shipment review, (4) not reassessing the HACCP plans, (5) not developing sanitary handling/re-conditioning procedures to protect incidentally dropped meat, and (6) inadequate PR/HACCP training or comprehension of establishment and official inspectors.

Carcasses were branded with green ink in Establishment 10.

Species identification monitoring was not being done.

Entrance Meeting

An entrance meeting was held at the Croatian Ministry of Agriculture and Forestry, Veterinary Administration headquarters in Zagreb on December 5, 2000. The meeting was attended by Dr. Mate Brstilo, Assistant to the Minister Director, Chief Veterinary Officer, Dr. Duro Majurdzic Head Veterinary Public Health Department (meat inspection), Dr. Dr. Nevenka Gašparac, Senior State (Federal) Veterinary Officer for meat and meat product inspection, Dr. Anđelco Gašparac, Head Veterinary Inspection Department, Professor Dr. Ivica Boban, national residues program, Dr. M. Ghias Mughal, Branch Chief, FSIS, International Audit Staff, official interpreter, and Dr. Hussain Magsi, FSIS, International Audit Staff Officer.

Following subjects were discussed:

1. Audit itinerary and travel arrangements.
2. Use of nutritional or geographic claim labels.
3. SSOPs, HACCP, *E. coli*, *Salmonella* spp., and *Listeria monocytogenes* testing.
4. National residue control program, and verification of Croatia's response to FSIS questionnaire on national residue monitoring and control program.
5. FSIS policy on 'listing and delisting' of establishments.
6. Compliance enforcement.

Headquarters Audit

There had been no organizational changes in Croatia's meat inspection systems.

To gain an accurate overview of the effectiveness of inspection controls, FSIS auditor requested that the inspection officials who normally conduct the periodic reviews for compliance with U.S. requirements lead the audits of the individual establishments. The FSIS auditor (hereinafter called “the auditor”) observed and evaluated the process.

The auditors conducted a review of the inspection system documents that included:

- Organizational structure of Animal Health and Veterinary Public Health Department.
- New initiatives and regulatory changes (Act, regulations, and policy).
- Internal audit/monthly supervisory reports.
- Food safety initiatives such as Sanitation standards and operating procedures (SSOPs), pathogen reduction (PR) for generic *E. coli* testing, *Salmonella* species, and *Listeria monocytogenes* testing, and Hazard Analysis and Critical Control Point (HACCP).
- Performance standards for sanitation, facilities, and equipment.
- Slaughter and processing inspection procedures and standards including labels approval, boneless inspection, etc.
- Epidemiology and zoonotic status and trends in Croatia including control of products from livestock disease conditions.
- National residue monitoring and control program.
- Livestock husbandry practices, including use of drugs and chemical and feed additives.
- Compliance enforcement.

No concerns arose as a result of the examination of these documents.

Government Oversight

All inspection veterinarians and food inspectors in establishments certified by Croatian to export meat product to the United States were full-time or part-time employees receiving no remuneration directly from either industry or establishment personnel. All U.S.-certified establishments are provided continuous inspection.

The Croatian Veterinary Service is vertically structured in the order - Ministry of Agriculture and Forestry’s Veterinary Directorate, five State (Federal) Veterinary Institutions for clinical support, laboratory diagnosis and food control testing, and 120 groups of contracted veterinarians for veterinary health and clinical veterinary health support to the public, and 21 county public health and veterinary health control stations. The Veterinary Directorate administers inspection system activities through five departments:

- Animal Health Protection
- Hygiene of Products of Animal Origin and for Veterinary Public Health
- Veterinary Inspection
- Border Veterinary Inspection
- Administration

In the Republic of Croatia there are over 730 meat and poultry establishments. The Directorate employs about 2,239 veterinarians in government headquarters; laboratories, universities, private practitioners, and 672 animal health assistants, usually with 2-3 years of training assist them. The inspection system supervises activities of 296 organizations, 1,212 establishments for slaughter, food processing, animal treatment, and storage of product, 103 establishments for animal feed production, and 44 border crossing inspection.

The 21 District/County Veterinary Inspection offices employ 86 country veterinary inspectors, and 547 authorized veterinarians. They are employed in four Regional Veterinary laboratories in Križevci, Rijeka, Split and Vinkovci, and Poultry Center in Zagreb. These laboratories in conjunction with Central Veterinary Diagnosis Laboratory in Zagreb are responsible for diagnostics, food hygiene, chemical and animal feed analysis activities, providing clinical assistance to the public, and conduct federally planned monitoring/sampling, and conducting compliance enforcement investigations. The Central Veterinary Laboratory through the Veterinary directorate coordinates animal health diagnosis, and analysis for residues and animal feeds, and provides analytical confirmation and specialty support to 21 Counties/districts.

The Croatian Veterinary Institute is comprised of 12 diagnostic/analytical departments: pathology, bacteriology, virology, parasitology, immunology, mastitis, foodstuffs hygiene, animal feed hygiene and feeding, chemistry, determination of residues, pharmacology, and zoo-hygiene. The Poultry Center is comprised of six departments: pathology, bacteriology, virology, mycology and mycotoxicology, animal feed, and biotechnology.

There are 44 Border Inspection points port of entry to control movement import and export of products and livestock at the Slovenia, Hungary, Yugoslavia, Bosnia and Herzegovina border crossings, seaports, airports, and mail system.

Establishment Audits

Establishments 10 and 139 were certified to prepare and export meat products to the United States. Both were on-site audited, and were determined acceptable. With the exception of deficiencies discussed in the report, the inspection and establishment system controls were in place to prevent, detect and control contamination and adulteration of the product.

Laboratory Audits

The auditors visited Croatian Veterinary Institute (CVI) and its associated microbiology and residue control laboratories in Zagreb, and Regional Veterinary Laboratories in Križevci and Rijeka. During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to the U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories
2. Inter-laboratory quality assurance procedures, including sample handling
3. Methodology

The CVI is a scientific-research and diagnostic institution. It manages five regional laboratories – Veterinary Institute in Split, Rijeka, Vinkovci, Krizevci, and Poultry Center in Zagreb. The principal mission includes animal health protection, jurisdiction over and control of domestic and international livestock movement, product of animal origin, animal feed and veterinary drugs. The research activity includes aspects of broad veterinary issues, animal husbandry, human health safety/food control and testing and environmental protection.

The responsible officials discussed biologics and animal drugs approval, implementation, monitoring and testing of samples for authorized biologics and medicaments, manufacturing and marketing of animal feeds, and control by District/County Animal Health and Food Control Stations. The laboratory analytical results were made available for verification.

The regional laboratories were well equipped and staffed with competent and qualified staff. These labs routinely analyze samples for microorganisms such as *E. coli*, *Salmonella* species, total plate counts, etc., food and meat products, food additives, animal feed stuffs and supplements, chlorinated hydrocarbons, trace elements, aflatoxins, mycotoxins, and microbiological and physico-chemical analysis of water. The Rijeka laboratory also handled marine fauna microbiological testing. The Rijeka laboratory lacked adequate personnel, equipment and facilities to carry out a vast sampling program, computerized tabulations and maintaining the record keeping instruments, and needed upgrading of some of the analytical equipment.

During a visit to a District/Country Veterinary Office, and a visit to a swine breeding farm, and an animal feed facility located in Dubrovnik, Zagreb county, the auditors were also briefed on the national system on clinical veterinary health public support, monitoring of federal disease control, sampling for food control monitoring, national identification of livestock, monitoring and control of feed additives and drugs, and residue withdrawal and guarantees, and animal health monitoring and medicaments use control programs. The discussions were candid, professionally sound and impressive, records were made available for verifications.

The auditor determined that official monitoring and control systems were in place for sampling procedures, analytical procedures, quality assurance procedures, and review procedures. The analytical methods used were standard, or internationally validated. Deficiency noted during the previous FSIS audit in November 1999 on intra-laboratory check samples frequency had been corrected.

Establishment Operations by Establishment Number

The following operations were being conducted in U.S.-certified:

Establishment 10 – beef and pork slaughter, curing/smoking, cooking and canning
Establishment 39 - beef and pork slaughter, curing/smoking, cooking and canning

SANITATION CONTROLS

Based on the on-site audits of establishments, Croatia's inspection system had controls in place for water potability records; chlorination procedures, back-siphonage prevention; hand washing facilities; sanitizers; separation of operations; pest monitoring and control; temperature control; lighting; work space; dry storage areas; personal dress, habits, and hygiene; equipment sanitizing; and product storage.

However, procedures for sanitary handling and re-conditioning of incidentally dropped meat were not available in either establishment (Ests. 10 and 139).

Sanitation Standards Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

No variances were noted during the audit.

ANIMAL DISEASE CONTROLS

Croatia's appears to have a well-organized and nationwide coordinated veterinary health and meat inspection system. The controls were in place to ensure adequate animal identification, antemortem and postmortem inspection procedures, carcass and parts disposition, and procedures for sanitary handling of product. The auditor audited official documents and visited the following program areas to reach this conclusion.

Croatian on-going national disease control programs include vaccination against hog cholera, tuberculosis and brucellosis testing of cattle and swine, and rabies vaccination of dogs and cats.

Croatia is free from List A diseases: Foot and Mouth, rinderpest, sheep and goat pox, Newcastle disease, and hog cholera. Diseases such as swine vesicular disease, vesicular stomatitis, Pestes des petis ruminant, contagious bovine pleuropneumonia, lumpy skin disease, Rift Valley fever, bluetongue, and African swine fever have never been recorded. Other disease conditions, such as echinococcosis, leptospirosis, rabies, paratuberculosis, bovine babesiosis, brucellosis (except in bovines), tuberculosis (bovine and porcine), cysticercosis, enzootic bovine leukosis, malignant catarrhal fever, trichinosis, swine reproductive and respiratory syndrome exist in variable intensity. It was determined that livestock husbandry practices, and the disease control program in Croatia were effective

According to Croatian Institute for Public Health, Zagreb, the cases of animal disease origin (zoonosis) in human population reported during 1999 included echinococcosis (17), leptospirosis (131), Q fever (20), bovine cysticercosis (3), trichinellosis (258), and salmonella infection (4,121).

U.S. Animal Plant and Health Inspection Service (APHIS) prohibits the use of beef product of Croatian origin in preparation of beef product intended for U.S. market. Croatia imports beef from Australia for preparation of U.S. export product. *Bovine spongiform encephalopathy* has not been recorded in Croatia.

Animal Identification

Identification (ear tagging/markings) of cattle, swine, sheep, goats, and canines is mandatory. Identification ear tags are issued by and the records maintained by Center for Reproduction in Livestock Breeding of Croatia.

Croatia has an effective and traceable livestock identification system.

RESIDUE CONTROLS

The auditors conducted an in-depth audit of Croatia's national residue control program to verify information provided by Hungarian Government in February 2000 in response to an FSIS questionnaire using a checklist on "Criteria for Assessing the Adequacy of the Residue Control Program for Meat, Poultry, and Egg Products". The criteria used for assessing the adequacy includes verification of information on the background, organization and legal authority, residue plan, residue plan operations, monitoring laboratories, and compliance and enforcement.

Discussions were held with responsible officials for animal Health and Food Control in Zagreb, and other officials associated with national residue control and monitoring program. The discussions focused on (1) identifying and evaluating drugs, pesticides and other chemical compounds of concern by slaughter class and/or egg product, (2) capability to analyze compounds of concern reliability, (3) appropriate regulatory follow-up of reports of violative tissue residues in meat, poultry and egg product, (4) collection, analysis, and reporting of these activities, and (4) anticipated testing plan to analyze compounds of concern for reliability for specific slaughter classes and/or egg products for a specified time period.

The auditor also visited a private livestock farm located in Zagreb County, discussed husbandry and animal health practices with responsible County Veterinary officials. The observations and records review indicated that sufficient controls existed for inventories and authorized acquisition/use of veterinary drugs and supplemental compounds/feed additives, and withdrawal time before slaughtering.

The auditors visited Croatian Veterinary Institute (CVI) in Zagreb, and audited residues and microbiological analytical results. CVI is comprised of laboratories for analyses of trace elements, pesticides, and veterinary drugs. All FSIS required compounds including carbadox and clenbuterol were being tested.

The auditor determined that Croatia had an effective residue control program and met U.S. requirements.

SLAUGHTER/PROCESSING CONTROLS

The Croatian inspection system had controls in place to ensure adequate animal identification; antemortem inspection procedures; antemortem disposition; humane slaughter; postmortem inspection procedures; postmortem disposition; restricted product control; pre-boning trim, boneless meat inspection; ingredient identification; control of restricted ingredients; formulations; packaging materials; inspector monitoring; processing schedules; processing equipment and records; empty inspection and filling procedures; container closure examination; post-processing handling; processing defect action-plan; and processing control-inspection.

HACCP Implementation

The establishments approved to export meat products to the U.S. were required to have developed and implemented a HACCP system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

In both establishments, official veterinary inspectors and establishment PR/HACCP responsible employees had no formal training. The reassessment of HACCP plans had also not been performed.

Pre-shipment verification reviews were not being performed. The establishment considered *Listeria monocytogenes* as a hazard likely to occur in ready-to-eat product, but had not developed and implemented HACCP requirements.

Testing for generic *E. coli*

Croatia has adopted the FSIS regulatory requirements for *E. coli* testing.

Establishments 10 and 139 were required to meet basic FSIS regulatory requirements for *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The sponge-sampling method was used, but the results of the tests were being recorded on a process control chart according to excision evaluation method. This deficiency was also noted during previous FSIS audit.

ENFORCEMENT CONTROLS

Inspection System Controls

The establishments systems conduct boneless meat reinspection, shipment security, including shipment between establishments, and the prevention of commingling of product intended for export to the United States with domestic product.

Residue Controls

Croatia's national residue testing plan for FY 2000 was being followed and was on schedule. The Croatian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures, storage and use of chemicals.

Three samples were found to exceed action level for cadmium during the year. The inspection system investigated the incidences, collected additional samples from the suspect herds/farms and animal feed and water, but found them negative.

Testing for *Salmonella* species

Establishments 10 and 139 were required to meet the basic FSIS regulatory requirements for *Salmonella* species testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The *Salmonella* species-testing program was audited and found to meet the FSIS determined equivalence. The inspection service collected samples. In case of positive case, product is identified, re-called if available, and confiscated for further action. Future shipments are withheld subject to laboratory analyses clearance. Investigation is conducted to determine root-cause(s) of product adulteration.

Testing for *Listeria monocytogenes*

The Bacteriology Laboratory at the Croatian Veterinary Institute routinely performed *Listeria monocytogenes* monitoring of the fresh beef matrices (brain, kidney, liver, spleen and muscle), pork fresh matrices (brain, kidneys, livers, muscle, lungs and lymph nodes), and ready-to-eat canned product. The Veterinary Directorate determined the frequency of sampling by official inspectors, and action for violation. The laboratory analyzed 21 fresh beef samples, 21 fresh pork samples, 48 canned product samples during CY 2000. All samples were negative.

However, the establishment considered *Listeria* a hazard likely to occur, but had not included in its HACCP plan.

Carcass Branding Ink

Carcasses in Establishment 10 were being branded with green ink.

Species Verification Testing

At the time of this audit, Croatia was not exempt from species verification-testing requirement. However, the verification testing was not being done. Both establishments deboned and processed beef and pork products.

It was learned that there were no species identification testing provisions in the Croatian Law. The testing was conducted in Croatian Veterinary Institute only when requested by the in-plant inspectors. It was stated that inspection service had discussed this issue with FSIS auditor during November 1999 audit, and had agreed to develop testing procedures for continued monitoring. The option had been evaluated, and the testing procedure to be used would be started very shortly.

Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system to each establishment certified as eligible to export to the United States, not less frequently than one such visit per month, during any period when the establishment is engaged in producing products that could be used for exportation to the United States.

Responsible State/Federal Senior Veterinary Officers conducted U.S.-certified establishment reviews infrequently, some time monthly and some time every other month. The supervisory Country Veterinary Officers also performed in-depth establishment audits from time to time.

Enforcement Activities

Each County's field staff officers provide livestock transportation certificates, verify withdrawal of drugs before slaughter, monitor and control additives and regulated drugs administration to the livestock and use in feed stuffs, monitor rendering facilities, and investigate violations of residue and other regulatory requirement. Violations are reported to police for legal action, and fines. The compliance enforcement action pertaining to product confiscation, fines, and imprisonment are legislated. It was stated that actions are taken when laws are transgressed.

FSIS Quarterly Regulation and Enforcement Report (April - June 2000) were presented to the meat inspection officials. The government was requested during the entrance meeting to provide compliance enforcement information.

Dr. Nevenka Gašparac provided an excerpt and tabulated information on compliance enforcement activity in Croatia during FY-2000, and was reviewed.

During 1999, 3,207 violations and 12 criminal cases were recorded for breach of veterinary inspection system requirements for food product of animal origin. In 2000, according to the provisions of relevant Croatian national laws and regulations (*Report on the 'Work of authorized veterinarians according to the District'*), 9,968 cases for violation of inspection laws had been recorded and investigated. Of these 493 cases were recommended for regulatory punitive action, and one for criminal action.

The authorized veterinarians also rendered 6,516 verbal and 3,572 written warnings and took appropriate regulatory action for violations of the inspection requirements. In order to assure safety of products of animal origin and animal feeds, 41,009 samples were collected for routine analysis, and 489 samples for confirmatory or surveillance purposes. No violations were found during 2000. The violators could be fined according to severity of criminal offense and amount of product involved. The fine range from Croatian Kuna 7,000 to 20,000, and up to one-year incarceration.

Exit Meeting

An exit meeting was conducted in Zagreb on December 12, 2000, and was attended by Drs. Mate Brstilo, Duro Majurdzic, Anelco Gašparac, Nevenka Gašparac, M. Ghias Mughal, Hussain Magsi, and Ms. Branka Rajkovic (professional interpreter).

The auditors discussed the findings and observations made during the audit. These specifically included deficiencies for HACCP, *Listeria* as a hazard likely to occur in ready-to-eat product, pre-shipment verification, *E. coli* evaluation criteria and charting of results, pre-shipment verification, HACCP plans re-assessment, HACCP training, and species identification testing.

Dr. Brstilo appreciated FSIS auditor's effort in explaining the PR/HACCP philosophy, rules, and discussed difficulties in interpretation and preparation of plans, and understanding of the implementation requirements of PR/HACCP rule. He also stated that under a 'World Bank Grant', they were going to send five supervisory officials in February 2001, and 10 County and in-plant veterinary officers to College Station, Texas for HACCP training program offered by the 'HACCP Alliance Group'.

The inspection officials stated that:

1. Copy of FSIS previous audit in November 1999 was not received. Therefore certain FSIS's PR/HACCP requirements were not fully understood. However, official guidelines had been issued to the establishments and the field staff to resolve inconsistencies in the PR/HACCP plan for implementation for reassessment, pre-shipment verification, evaluation criteria development for *E. coli* testing, and *Listeria* testing for ready-to-eat product.
2. Immediate corrective measures had been taken to develop and implement written procedures to preclude contamination of incidentally dropped meat.

3. Croatian law required food grade ink irrespective of color. Therefore use of green ink was allowed in Establishment 10. However, use of green ink had been discontinued immediately following the audit.
4. The testing would be started immediately.

CONCLUSION

The overall establishment system was determined to be equivalent to that which FSIS requires in domestic establishments. However, inconsistencies in PR/HACCP plans and their implementation existed, which were being addressed by the inspection service. Responsible personnel had been scheduled for formal HACCP training in Texas. It was stated that species identification analysis, branding ink, and re-conditioning of incidentally contaminated product had been corrected.

The national animal health and residue control programs were effective and met U.S. requirements.

Croatia has an extensive network of regulatory compliance enforcement systems at local, county and national level. The deficiencies encountered during this audit were adequately addressed to the auditor's satisfaction.

(signed)Hussain Magsi, DVM, MS
Hussain Magsi, DVM, MS
International Audit Staff Officer

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for generic *E. coli* testing
- D. Data collection instrument for *Salmonella* species testing
- E. Laboratory audit forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available).
- H. FSIS Response(s) to Foreign Country Comments (when it becomes available).

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of the establishments visited on-site were evaluated as follows:

Est. No.	1. Written program addressed	2. Pre-op sanitation addressed	3. Operational sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible individual identified	7. Documentation done daily	8. Dated and signed
10	√	√	√	√	√	√	√	√
139	√	√	√	√	√	√	√	√

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. No	1.Flow diagram	2.Hazard analysis done	3. All hazards identified	4. Use and users included	5. Plan for each hazard	6. CCPs for all hazards	7.Monit. critical limits, and freq. specified	8.Corrective actions described	9. Plan validated	10. Adeq. Verific. Proc.	11. Adequacy of documentation.	12. Dated and signed
10	√	√	*	√	√	√	√	√	√	**	√	√
139	√	√	*	√	√	√	√	√	√	**	√	√

* *Listeria monocytogenes* as hazard likely to occur was analyzed, but the requirements were not being met.

** Reassessment of HACCP plans was not performed, and pre-shipment verification was not being done.

Data collection instruments for *E. coli* testing

All slaughter establishments were evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the equivalent criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

The results of these evaluations were as follows:

Est. No.	*1. Written procedure	2. Sample collector designated	3. Sampling location given	4. Predominant spp. sampled	5. Sampling at required frequency	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
10	*	√	√	√	√	√	√	√	√	*
139	*	√	√	√	√	√	√	√	√	*

*The sponge-sampling method is used, but the results of the tests are being recorded on a process control chart showing the most recent test results according to excision evaluation method.

Data Collection instruments for *Salmonella* spp. Testing

All slaughter establishments were evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* species testing were met, according to the equivalent criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

*The results of these evaluations were as follows:

Est. No.	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper production	7. Violative Est. stop operations
10	√	√	√	√	√	*
139	√	√	√	√	√	*

* Product is identified, re-called if available, and confiscated for further action. Future shipment is withheld subject to laboratory analyses clearance.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS				REVIEW DATE 12-11-00		NAME OF FOREIGN LABORATORY CROATIAN VETERINARY INSTITUTE									
FOREIGN COUNTRY LABORATORY REVIEW															
FOREIGN GOV'T AGENCY VETERINARY SERVICE/DIRECTORATE			CITY & COUNTRY ZAGREB, COATIA			ADDRESS OF LABORATORY ZAGREB									
NAME OF REVIEWER Dr. Hussain Magsi			NAME OF FOREIGN OFFICIAL Drs. Mirko Lojkic, Vitomar Bilic, et. al												
Residue Code/Name			100	111	200	202	300	400	500	800	Sal	Ecol			
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A	A	A	A	A	A	A	A	A	A		
	Sampling Frequency	02		A	A	A	A	A	A	A	A	A	A		
	Timely Analyses	03		A	A	A	A	A	A	A	A	A	A		
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O	O		
	Interpret Comp Data	05		A	O	O	O	O	O	O	O	O	O		
	Data Reporting	06		A	A	A	A	A	A	A	A	A			
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A	A	A			
	Correct Tissue(s)	08		A	A	A	A	A	A	A	A	A			
	Equipment Operation	09		A	A	A	A	A	A	A	A	O	O		
	Instrument Printouts	10		A	A	A	A	A	A	A	A	O	O		
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A	A	A	O	O		
	Recovery Frequency	12		A	A	A	A	A	A	A	A	O	O		
	Percent Recovery	13		A	A	A	A	A	A	A	A	O	O		
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	A	A		
	All analyst w/Check Samples	15		A	A	A	A	A	A	A	A	A	A		
	Corrective Actions	16		A	A	A	A	A	A	A	A	A	A		
	International Check Samples	17		O	A	A	A	A	A	A	A	A	A		
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O	O	O	O			
OTHER REVIEW		19	EVAL. CODE												
		20													
SIGNATURE OF REVIEWER									DATE						

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE	ESTABLISHMENT NO. AND NAME		CITY
FOREIGN PLANT REVIEW FORM		12-5-00	EST. 10, PIK VRBOVEC MESNA INDUSTRIJA		VRBOVEC
					COUNTRY CROATIA
NAME OF REVIEWER Dr. Hussain Magsi		NAME OF FOREIGN OFFICIAL Dr. Nenenka Gasparac		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below)					
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention		28 U	Formulations 55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing		29 A	Packaging materials 56 A
Water potability records	01 A	Product handling and storage		30 A	Laboratory confirmation 57 A
Chlorination procedures	02 A	Product reconditioning		31 M	Label approvals 58 A
Back siphonage prevention	03 A	Product transportation		32 A	Special label claims 59 A
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM			Inspector monitoring 60 A
Sanitizers	05 A	Effective maintenance program		33 A	Processing schedules 61 A
Establishments separation	06 A	Preoperational sanitation		34 A	Processing equipment 62 A
Pest --no evidence	07 A	Operational sanitation		35 A	Processing records 63 A
Pest control program	08 A	Waste disposal		36 A	Empty can inspection 64 A
Pest control monitoring	09 A	2. DISEASE CONTROL			Filling procedures 65 A
Temperature control	10 A	Animal identification		37 A	Container closure exam 66 A
Lighting	11 A	Antemortem inspec. procedures		38 A	Interim container handling 67 A
Operations work space	12 A	Antemortem dispositions		39 A	Post-processing handling 68 A
Inspector work space	13 A	Humane Slaughter		40 A	Incubation procedures 69 A
Ventilation	14 A	Postmortem inspec. procedures		41 M	Process. defect actions -- plant 70 A
Facilities approval	15 A	Postmortem dispositions		42 A	Processing control -- inspection 71 A
Equipment approval	16 A	Condemned product control		43 A	5. COMPLIANCE/ECON. FRAUD CONTROL
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control		44 A	Export product identification 72 A
Over-product ceilings	17 A	Returned and rework product		45 A	Inspector verification 73 A
Over-product equipment	18 A	3. RESIDUE CONTROL			Export certificates 74 A
Product contact equipment	19 A	Residue program compliance		46 A	Single standard 75 A
Other product areas (inside)	20 M	Sampling procedures		47 A	Inspection supervision 76 A
Dry storage areas	21 A	Residue reporting procedures		48 A	Control of security items 77 A
Antemortem facilities	22 A	Approval of chemicals, etc.		49 A	Shipment security 78 A
Welfare facilities	23 A	Storage and use of chemicals		50 A	Species verification 79 U
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL			"Equal to" status 80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim		51 A	Imports 81 O
Personal dress and habits	25 A	Boneless meat reinspection		52 A	SSOPs 82 A
Personal hygiene practices	26 A	Ingredients identification		53 A	PR/HACCP 83 M
Sanitary dressing procedures	27 A	Control of restricted ingredients		54 A	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	12-5-00	EST. 10, PIK VRBOVEC MESNA INDUSTRIJA	VRBOVEC
			COUNTRY
			CROATIA
NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL		EVALUATION
Dr. Hussain Magsi	Dr. Nenenka Gasparac		<input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable

COMMENTS:

20/28. The carcass work-stands were not provided with foot-guards to protect against contamination. This was a repeat deficiency - noted during previous FSIS audit.

31/83. Written procedures for sanitary handling and re-conditioning of incidentally dropped/contaminated meat were not available.

41. Inspected and passed carcasses were branded with green ink.

79. Species verification testing was not being done.

83. - Sampling for *E. coli* was being done by sponge method, but normal process control limits incorrectly used for excision method.

The establishment failed to use process control technique (charting or plotting the results overtime) to determine what variation in the test results was within normal limits. This was a repeat deficiency- noted during previous FSIS audit.

- In-plant official inspectors, and official supervisors were not trained in PR/HACCP.

-The pre-shipment verification reviews were not being done.

- *Listeria monocytogenes* was determined to be a hazard likely to occur, but establishment did not develop HACCP plan.

Inspection service was collecting monitoring samples.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE	ESTABLISHMENT NO. AND NAME		CITY
FOREIGN PLANT REVIEW FORM		12-6-00	EST. 139, DANNICA MEAT INDUSTRY		KOPRIVNICA
NAME OF REVIEWER Dr. Hussain Magsi		NAME OF FOREIGN OFFICIAL Dr. Nevenka Gasparac		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below)					
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention		28 A	Formulations A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing		29 A	Packaging materials A
Water potability records	01 A	Product handling and storage		30 A	Laboratory confirmation A
Chlorination procedures	02 A	Product reconditioning		31 M	Label approvals A
Back siphonage prevention	03 A	Product transportation		32 A	Special label claims A
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM			Inspector monitoring A
Sanitizers	05 A	Effective maintenance program		33 A	Processing schedules A
Establishments separation	06 A	Preoperational sanitation		34 A	Processing equipment A
Pest --no evidence	07 A	Operational sanitation		35 A	Processing records A
Pest control program	08 A	Waste disposal		36 A	Empty can inspection A
Pest control monitoring	09 A	2. DISEASE CONTROL			Filling procedures A
Temperature control	10 A	Animal identification		37 A	Container closure exam A
Lighting	11 A	Antemortem inspec. procedures		38 A	Interim container handling A
Operations work space	12 A	Antemortem dispositions		39 A	Post-processing handling A
Inspector work space	13 A	Humane Slaughter		40 A	Incubation procedures A
Ventilation	14 A	Postmortem inspec. procedures		41 A	Process. defect actions -- plant A
Facilities approval	15 A	Postmortem dispositions		42 A	Processing control -- inspection A
Equipment approval	16 A	Condemned product control		43 A	5. COMPLIANCE/ECON. FRAUD CONTROL
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control		44 A	Export product identification A
Over-product ceilings	17 A	Returned and rework product		45 A	Inspector verification A
Over-product equipment	18 A	3. RESIDUE CONTROL			Export certificates A
Product contact equipment	19 A	Residue program compliance		46 A	Single standard A
Other product areas (inside)	20 A	Sampling procedures		47 A	Inspection supervision A
Dry storage areas	21 A	Residue reporting procedures		48 A	Control of security items A
Antemortem facilities	22 A	Approval of chemicals, etc.		49 A	Shipment security A
Welfare facilities	23 A	Storage and use of chemicals		50 A	Species verification A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL			"Equal to" status A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim		51 A	Imports O
Personal dress and habits	25 A	Boneless meat reinspection		52 A	SSOPs A
Personal hygiene practices	26 A	Ingredients identification		53 A	PR/HACCP M
Sanitary dressing procedures	27 A	Control of restricted ingredients		54 A	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 12-6-00	ESTABLISHMENT NO. AND NAME EST. 139, DANNICA MEAT INDUSTRY	CITY KOPRIVNICA
			COUNTRY CROATIA
NAME OF REVIEWER Dr. Hussain Magsi	NAME OF FOREIGN OFFICIAL Dr. Nevenka Gasparac	EVALUATION <input checked="checked" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

31/83. Written procedures for sanitary handling and re-conditioning of incidentally dropped/contaminated meat were not available.

79. Species verification testing was not being done.

83. - Sampling for *E. coli* was being done by sponge method, but normal process control limits incorrectly used for excision method. The establishment failed to use process control technique (charting or plotting the results overtime) to determine what variation in the test results was within normal limits. This was a repeat deficiency- noted during previous FSIS audit.

- In-plant official inspectors, and official supervisors were not trained in PR/HACCP.
- The pre-shipment verification reviews were not being done.
- *Listeria monocytogenes* was determined to be a hazard likely to occur, but establishment did not develop HACCP plan.

Inspection service was collecting monitoring samples.



REPUBLIKA HRVATSKA
MINISTARSTVO POLJOPRIVREDE I ŠUMARSTVA
Veterinary Administration

10000 Zagreb, Ul. grada Vukovara 78, P.P. 1034
Telefon: 61 06 111, Telefax: 61 09 200

Class: 322-01701/01/460
File No.: 525-06-01-02/NG/
Zagreb, June 1, 2001

USDA/FSIS
Washington DC 20250
14th & Independence Avenue, SW
To: Sally Stratmoen, Acting Director
International Policy Staff

Re: Reply by the competent authority of the Republic of Croatia to the Draft Report of the USDA/FSIS inspection team on the findings on the spot during the inspection carried out from 4th-12th December 2000 in the Republic of Croatia

Dear Sirs,

By this letter we would like to acknowledge the receipt of the Draft Report (23rd April 2001) on the findings of the veterinary inspection carried out in the Republic of Croatia in the period from 4th to 12th December 2000 and to give our reply observing the set period of time.

We have pleasure to submit our action plan the implementation of which followed immediately after the completion of inspection by the USDA/FSIS inspection team in the republic of Croatia and recommendations provided during the telephone conference by your authorities, in order to enable us to remove deficiencies mentioned in the Report.

At the same time, we confirm the receipt of the 1999 Report and would like to thank you very much for all the instructions given to us as well as for an open professional cooperation extended by your competent authorities.

Sincerely yours,

Assistant to the Minister- Director



Encl.: Reply to the Draft Report 2000

- C.C.: 1. USDA/FSIS/TSC, Suite 300, Landmark Center,
1299 Farnam Street, Omaha, NE 68102
2. American Embassy, Office of Agricultural Affairs,
Boltzmanngasse 16, A-1091 Vienna, Austria
Agricultural Counselor, Mr. Robert. H. Curtis
3. Embassy of the USA, Zagreb, Andrije Hebranga 2
Economic Officer, U.S. Embassy – Jill Byrnes
4. Archives - here

Reply to the Draft Final Report on the inspection team's findings during the inspection carried out in the Republic of Croatia in the period from 4th to 12th December 2000

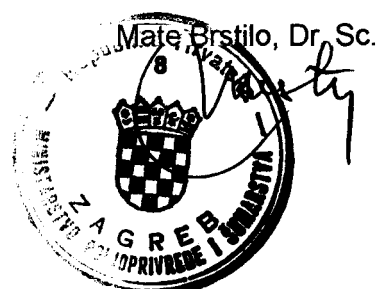
This competent authority provided a verbal information about the measures taken during the telephone conference with USDA/FSIS held on 8th and 12th March 2001, as well as by way of written documents sent till 10th March 2001 concerning the steps taken in order to remove deficiencies.

By this reply to the received Report we would like to inform you about the plan of action and measures taken for rectifying of deficiencies mentioned in inspection team's Report following the routine inspection and during the official verification of the equivalency of the Croatian meat inspection system, carried out in December 2000.

Reply by the central competent authority of the Republic of Croatia to the Draft Final:

- as from 1st March 2001 control has been introduced in the export establishments on the pigs and cattle slaughter lines in order to prevent faecal contamination by application of SPC;
- in the export establishments written procedures have been introduced recording the handling of meat and carcasses dropped on the floor;
- in the export establishments, as from 9th February 2001, pre-shipment control has been introduced, which is recorded and verified by the competent responsible person and veterinary inspector on the form prescribed for that purpose;
- the establishments are carrying out regular reassessment of their HACCP Plans once a year (for the previous year at the beginning of the current year);
- the risk of *Listeria monocytogenes* presence in "ready to eat" products has also been reassessed in the establishments;
- in February 2001, veterinary inspectors from the export establishments were included in the training at College Station/USA/Texas;
- in one of the establishments (No. 10) control has been continued over the identification of species (kind of meat) in the national laboratory of the Croatian Veterinary Institute in Zagreb (evident from the findings in the 1999 Report) and in the other establishment (No. 139) the implementation of control has started in February 2001, until the final decision by your competent authorities about our request for exemption from the species identification. (In this connection please find enclosed a copy of the USDA competent body's letter and the request for exemption by the competent authorities of the Republic of Croatia, dated 14th February 2000);
- technical deficiencies in one of the establishments (No. 139) at the platforms in contact with carcasses in the pigs and cattle slaughterhouse, were successfully removed prior to 2nd January 2000;
- the HACCP Plan on the pork and beef boning line in one of the export establishments (No. 139) has been implemented as from 2nd February 2001.
- in one of the establishments (No. 10) the blue/green ink, used for marking of hygienically safe bovine halves, was immediately (during the inspection itself) put out of use.

Assistant to the Minister- Director



Encloser: Request for exemption-doc.



Embassy of the United States of America

REPUBLIKA HRVATSKA
525 — MINISTARSTVO POLJOPRIVREDE I
ŠUMARSTVA

Primalina: / 1 -02- 2000	
322-01/00-01/101	
Uredžbeni broj	Prih. Vrij.

Office of Agricultural Affairs
American Embassy
Boltzmanngasse 16
A-1091 Wien

January 25, 2000

Dr. Mate Brstilo
Director of Veterinary Directorate
Ministry of Agriculture and Forestry
A. Vukovar 78
41000 Zagreb
Croatia

Dear Dr. Brstilo:

We received from Mr. Mark Manis, Director, International Policy Division (IPD), Office of Policy, Program Development and Evaluation (OPPDE), USDA/FSIS a message concerning species verification testing of fresh and cooked meat. We are forwarding this message for your action.

Sincerely,

Allan P. Mustard
Agricultural Counselor

Enclosure



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

JAN 18 2000

Dr. Mate Brstilo, Director
Veterinary Administration
Ministry of Agriculture and Forestry
Utica grada Vukovra 78
10000 Zabreb, Croatia

Dear Dr. Brstilo:

All countries that are eligible to export meat or poultry to the United States must conduct species verification testing of fresh and cooked products intended for shipment to the U.S. market. The Food Safety and Inspection Service (FSIS) initiated the requirement for species verification testing of fresh meat in 1981. Species verification testing for cooked meat products was required in 1988. The purpose of this letter is to clarify FSIS policy for exempting foreign countries from routine species verification testing.

In 1991, FSIS sent a cable to all eligible countries informing them that they could be exempted from routine species verification testing if they had satisfactory controls in place to assure that commingling of species did not occur. The conditions for exemption included all of the following:

1. Carcasses and products are transported between establishments in devices which are sealed with a tamper detectable inspection seal applied by the Inspection Service at the originating establishment and broken by the Inspection Service at the receiving establishment.
2. Brands and sealing devices used by the Inspection Service to identify and seal product are kept under Inspection Service control.
3. Establishments are under continuous Inspection Service supervision while operating. No operations may take place without Inspection Service supervision.
4. Only one species of livestock or meat is allowed in the slaughter or processing areas at one time.
5. Product must be exported to the United States in a cargo container sealed by the Inspection Service.

Please advise FSIS in writing within 30 days after the date this letter is delivered, whether your country is conducting routine species verification testing as required or if you wish to request an exemption from this testing. The conditions noted above must be met before an exemption will be granted.

Your response should be directed to:

Director, International Policy Division
Food Safety and Inspection Service, USDA
1400 Independence Avenue, SW
Room 4434 South
Washington, DC 20250

If your country requests an exemption and if it is granted, FSIS will verify the exemption, conditions outlined above during our next audit of your inspection system. For further information or questions, please contact Ms. Nancy Goodwin at (202) 720-6400; fax (202) 720-7990.

Sincerely,

A handwritten signature in dark ink, appearing to read "Mark Manis". The signature is fluid and cursive, with the first name "Mark" and last name "Manis" clearly distinguishable.

Mark Manis, Director
International Policy Division
Office of Policy, Program Development
and Evaluation



REPUBLIKA HRVATSKA
MINISTARSTVO POLJOPRIVREDE I ŠUMARSTVA
Veterinary Administration

10000 Zagreb, Ul. grada Vukovara 78, P.P. 1034
Telefon: 61 06 111, Telefaks: 61 09 200

Class: 322-01/00-01/101
File No.: 525-06-00-02/NG/
Zagreb, February 14, 2000.

Director, International Policy Division
FSIS/ USDA
1400 Independence Avenue, SW
Room 4434 South
Washington, DC 20250

Subject: Request for an exemption from routine species verification testing of meat products -
exported from the Republic of Croatia to the USA market

Dear Dr.Manis,

The Ministry of Agriculture and Forestry of the Republic of Croatia - Veterinary Directorate has registered with central competent body -USDA/FSIS, two establishment for export to the USA market. These establishments have approved export numbers: No 10 and No 139. Both establishment comply with the conditions laid down by federal Meat Inspection Act and the conditions laid down in 327.2 (a).

By your letter of 25th January 2000 a possibility is provided for an exemption from routine species verification testing under the specified conditions. In this connection, we would like to inform you that the Republic of Croatia meets the required conditions and therefore would like to request exemption from this testing (Annex).

Under the cover of this letter please find the statement on the implementation of effective inspections and controls based on and organized in accordance with the Veterinary Law (Official Gazette No. 70/97), by which the commingling of raw materials-meats of various species is prevented.

Hoping that the respective exemption will be granted, we remain,



Sincerely yours,
Assistant to the Minister-Director
Mate Brstilo, Ph.D.

Encl.

Guaranties in respect of complying with the required conditions for an exemption from verification testing - tissue standardization.

ANNEX

Clarification on complying with the required conditions for exemption of the Republic of Croatia from tissue standardization for individual animal species, as follows:

1. Carcasses and products in the domestic traffic between the approved establishments, are transported by means of transportation which comply with the conditions laid down for transportation of such consignments, with the following verifications being carried out:

- 1.1. Veterinary-sanitary conditions and health status of the consignment;
Accuracy of the accompanying veterinary-sanitary documentation;
Compliance of the means of transportation with the required conditions;

1.2. In the approved establishments in the Republic of Croatia, loading, transshipment and unloading of consignments of meat and products of animal origin in domestic trading as well as in the trading over the state borders, is subject to obligatory veterinary-sanitary checks.

The obligatory veterinary-sanitary checks are carried out at the place of loading, transshipment and unloading of consignments and they include:

- checking of the accompanying documentation and the data in health certificate;
- identity verification for every consignment in order to establish whether the consignment comply with the data stated in the accompanying documentation;
- verification, the intention of which is to establish whether the stamps and official and health marks (identifying the establishment and the country of origin) are correctly applied to accompanying documents and a consignment (including respective veterinary certificate).

1.3. Consignments in the international trading are, along with satisfying the previously mentioned conditions, accompanied by the international certificate on animal health and sanitary safety of a consignment, which must be original, composed on the day of shipment, for one animal species and one kind of products, for one consignee, verified as prescribed and marked with a serial number.

1.4. Consignments exported from an approved establishment are sealed by an inspection seal, applied by veterinary inspection in the establishment, in order to avoid possible manipulations.

1.5. An authorised veterinarian keeps records of the performed veterinary-sanitary checks of consignment in domestic and international trading as well as of loading, transshipments, on the official forms HVI - I and HVI II.

2. Brands and sealing devices used by inspection service to identify product and seal a consignment are kept under the key in the official veterinary inspection premises in the establishment and they are responsibility of the inspection premises in the establishment and they are responsibility of the veterinary inspector in charge, who is known by his first and last name.

3. All export establishments in the Republic of Croatia are under continuous inspection service control and supervision (24 hours). In an establishment not a single operation in production may be carried out without veterinary inspection being present (Ante mortem insp., Post mortem insp., re-inspection of the meat, unloading, loading, ... etc.)

4. For slaughter and processing in export establishments there are separate lines for slaughter, cutting and processing for only one animal species.

5. When exported to USA, products are transported in a cargo container sealed by inspection service in an export establishment, bearing a seal with the approved establishment's number.

